



TasP

Antiretroviral treatment as Prevention - ANRS 12249  
! Zuphi! basini, uphihi! cecita! emi! nathi! for our health!

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00059977

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20130724

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130926

1. Patient details

TasP ID

16966

Name

G.T

Sex

Male

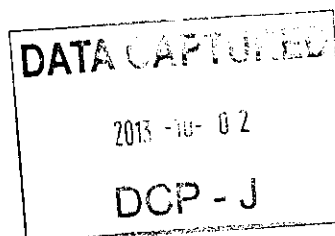
☒ Female

Date of birth

19790621

Enrolment date

20130114



2. Description of the reported SAE

CHRONIC HEPATITIS

Date of SAE onset

20130725

3. Complementary information

Patient was referred to hospital on 18/9/2013 having presented with worsening hepatitis. She was seen at hospital on 19/9/2013 and booked for a more specialised hospital (Ngwelezana hospital) for follow up progress when patient returns.

4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

☒ No

N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

	Generic Name	Dose	Frequency	New judgement of causality
1.	ATRIPLA <sup>300/200/600</sup>	300/200/600	daily	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.	Isoniazid	300mg	daily	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.	Pyridoxine	25mg	daily	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.	Vit. B. co	$\frac{c}{i}$	daily	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

## 7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

- 7a. According to the physician, is this SAE likely to be related to participation in the research? ☒ Yes ☐ No
- 7b. According to the physician, is this SAE related to any causes other than the research? ☐ Yes ☒ No  
*This includes the patient's medical history*  
☐ Describe

## 8. SAE Outcome

- Unknown to date ☐
- ☒ Ongoing ☐
- Improved ☐
- Worsened ☐
- Recovered ☐ → Date of recovery
- Recovered without sequelae
- or
- Recovered with sequelae ☐ Describe
- Another complementary SAE notification form must be submitted within 8 days from now.



## Physician reporting SAE Complementary Notification

Name DR OLUMUYIWA A. OLONG

Signature [Signature]

Date form completed 2013 09 26